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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/526,498 | 09/29/2005 | Bernard Bene | 07552.0055-00000 | 7337 |
| 22852 | 7590 | 05/01/2009 | EXAMINER | |
| FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 901 NEW YORK AVENUE, NW WASHINGTON, DC 20001-4413 | | | CHRISTIAN, MARJORIE ELLEN | |
| ART UNIT | | PAPER NUMBER | | |
| 1797 | | | | |
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| 05/01/2009 | | PAPER | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|---------------------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/526,498 | BENE ET AL. |
| | Examiner MARJORIE CHRISTIAN | Art Unit 1797 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 24 February 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-44 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-44 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Summary

1. This is the initial Office action based on the application filed March 3rd, 2005.
2. Claims 1-44 are pending and have been fully considered.

Election/Restrictions

3. Applicant's election without traverse of Group I, Claims 1-44 in the reply filed on 2/24/2009 is acknowledged.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Oath/Declaration

5. Applicant (Carl Reitz) has not given a post office address in the application papers as required by 37 CFR 1.33(a), which was in effect at the time of filing of the oath or declaration. A statement over applicant's signature providing a complete post office address is required.

Claim Objections

6. Claim 5 is objected to because of the following informalities: "required for achieving said 5 prescribed total dialysis". It appears that 5 is a typing error. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. Claims 2-4, 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It appears Applicant is drawing these claims to alternative expressions (i.e. Markush groups) however these claims are not drawn to the appropriate form of alternative expressions. Examples of appropriate alternative expressions that present no uncertainty or ambiguity with respect to the scope of clarity of the claims are shown in the MPEP 2173.05 (h) and include language such as "selected from the group consisting of A, B, and C". For the purposes of interpretation it is presumed that Applicant is drawing these claims to alternative expressions.

Claim Rejections - 35 USC § 102

8. Claims 1-37, 39, 41-44 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,258,027, STERNBY (hereinafter STERNBY).

As to Claims 1-36, STERNBY discloses a blood treatment unit (Fig. 1) with a semi-permeable membrane (3) with first and second compartments for blood and treatment liquid (C10/L43-47) and a controller (17). The controller monitors urea

concentration downstream of the treatment liquid side (18) and uses the measurements to manipulate and calculate various data parameters (C2/L24-67, C8/L16-42) associated with effective treatments. The sensor readings, data collected and data manipulations obtained from the controller are used to control various pumps, flow rates etc. (C9/L30-67 & C10/L59-67).

Claims 1-36 are drawn to and replete with functional and intended use language that does not structurally differentiate the controller. The controller of STERNBY is implicitly capable of manipulating the data from the sensor readings to determine the progress of the treatment (as shown above) and directing treatment based on sensor readings and data calculations (see claims 26-49 of STERNBY). The equations, data manipulations and data collection at different time intervals in the claims appear to be similar expressions as in the reference, but rearranged and using different notations. In any case, the mathematical expressions for calculating a parameter is not a patentable limitation in an apparatus as it does not structurally distinguish the claimed invention from the apparatus of STERNBY.

Additionally, it has been held that apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). A claim containing a “recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus” if the prior art apparatus teaches all the structural limitations of the claim. *Ex parte Masham*, 2 USPQ2d 1647 (Bd. Pat. App. & Inter. 1987). “Expressions relating the apparatus to

contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim." *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969). Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).

As to Claims 37, 39, STERNBY discloses measuring the conductivity of the treatment liquid on conduits downstream (18) of the treatment unit (Ref. 1) with a urea sensor/monitor (18).

As to Claim 41, STERNBY discloses that the dialysis machine is operated so that the treatment prescribed for the patient is fulfilled (C11/L10-12), which implies that the dialysis treatment is entered into the computer that controls the dialysis treatment, absent evidence to the contrary.

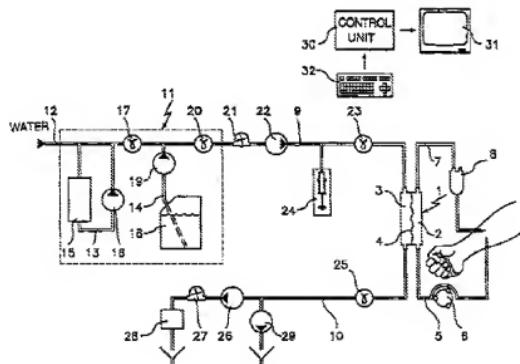
As to Claim 42, STERNBY discloses variable speed pumps that are controlled by the controller (C10/L60-65) the pumps include an ultrafiltration pump (Ref. 11).

As to Claim 43, STERNBY discloses the controller is associated with an alert device that activates if concentration curve (which is dependent on time) deviates from a predetermined threshold (Claim 23, 47).

As to Claim 44, STERNBY discloses the computer provides various concentration values related to the treatment (C11/L26-33).

9. **Claims 1-42, 44 are rejected under 35 U.S.C. 102(b) as being anticipated by US Patent No. 6,011,384, GOUX (hereinafter GOUX).**

As to Claims 1-36, GOUX discloses a controller for a blood treatment equipment (Abstract) comprising: a treatment unit (Fig. 1) including a semi-permeable membrane (4) separating the unit into a first (2) and second (3) compartment for the circulation of blood and a treatment liquid. The controller receives data, calculates a parameter that indicates the progress of the treatment, compares the calculated parameter with a reference value and generates an output signal responsive to the comparison that controls the operations performed by the equipment (C2/L50-C4/L14, Claims 12-13) based on conductivity measurements from a sensor (C7/L18-39). The controller apparatus controls and monitors the treatment based on the readings from the sensors and their subsequent data manipulation (C3/L27-40, C5/L31-39) at various time points during the treatment (C12/L48-57), resulting in a treatment that implicitly concludes when treatment is complete not when a set period of time has passed (C1/L31-50).



Claims 1-36 are drawn to and replete with functional and intended use language that does not structurally differentiate the controller. The controller of GOUX is implicitly capable of manipulating the data from the sensor readings to determine the progress of the treatment (as shown above) and directing treatment based on sensor readings and data calculations.

Further, it has been held that apparatus must be distinguished from the prior art in terms of structure rather than function. A claim containing a "recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus" if the prior art apparatus teaches all the structural limitations of the claim. Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established.

The equations, data manipulations and data collection at different time intervals in the claims appear to be similar expressions as in the reference, but rearranged, and using different notations. In any case, the mathematical expressions for calculating a parameter is not a patentable limitation in an apparatus as it does not structurally distinguish the claimed invention from the apparatus of GOUX.

As to Claims 37-40, GOUX discloses measuring the conductivity of the treatment liquid on conduits downstream (25) and upstream (23) of the treatment unit (Ref. 1, C12/L7-18) with a conductivity probes (C5/L29-35).

As to Claim 41, GOUX discloses a keyboard for entering pertinent information to the treatment and treatment parameters (Ref. 32, C5/L25-31).

As to Claim 42, GOUX discloses variable speed pumps that are controlled by the controller (C5/L32-38) the pumps include an ultrafiltration pump (Ref. 29, C5/L46-62).

As to Claim 44, GOUX discloses a monitor connected to a computing and control unit and keyboard (30-32) to display user entered data including blood flow rate, dialysis liquid flow rate, conductivity set values, to set treatment duration and weight loss (C5/L24-31).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- US Patent No. 6,648,845, GOTCH et al. discloses a controller for a blood treatment unit that measures and manipulates treatments based on sensor readings that indicate progress;
- US Patent No. 5,230,702 LINDSAY et al. discloses a dialysis optimization method and treatment that uses data measurements from a sensor during treatment to calculate various parameters in a controller, where the controller

uses the parameters to determine the progress of treatment and manipulate various factors that relate to treatment factors; and

- US Patent No. 5,024,756, STERNBY et al. discloses a dialysis system and method that uses measurements from sensors to control the operations and efficacy of the treatment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is (571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571)272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Krishnan S Menon/
Primary Examiner, Art Unit 1797